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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,526	10/27/2003	Mark E. Connell	112713-486	7262

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EXAMINER

DRODGE, JOSEPH W

ART UNIT	PAPER NUMBER
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1723

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/695,526

Applicant(s)

CONNELL ET AL.

Examiner

Joseph W. Drodge

Art Unit

1723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on October 27, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Drodge at telephone number 571-272-1140. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached at 571-272-1151. The fax phone number for the examining group where this application is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either private PAIR or Public PAIR, and through Private PAIR only for unpublished applications. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JWD

March 4, 2004


JOSEPH DRODGE
PRIMARY EXAMINER

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103 (a) and potential U.S.C. 102 (f) or (g) prior art under 35 U.S.C. 103 (a).

Claims 42-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lichtenstein patent 4,370,983 in view of Rubalcaba patent 4,898,578 and/or Kerns et al patent 4,756,706 (hereafter "Kerns").

Lichtenstein discloses a computer controlled medical care system that encompasses extracorporeal blood circulation and treatment systems including means for conducting dialysis treatment of the blood in which numerous parameters are monitored, displayed and controlled through the use of central processing units coupled to interactive data entry devices such as keyboards, monitoring units and alphanumeric, CRT or other types of display units (see column 22, lines 23-35; column 28, lines 60-65 and column 32, lines 62-67). These displays communicate adjustments needed for operation of components such as pumps and valves. The disclosed medical care system can include modules for conducting intravenous and drug infusion for patients in addition to hemodialysis, hemofiltration and a plurality of other medical procedures (column 5, line 34-column 6, line 24 and column 31, lines 12-33).

The claims all differ from Lichtenstein in requiring the system to be operably connected to a touch screen operable for displaying information corresponding to a setting of a parameter and operable to display an indicium permitting a user to perform at least one step of a procedure for changing the setting of the parameter (i.e. operable for controlling the parameter). Although Lichtenstein does disclose use of data processing components generally in column 8, lines 1-16 and column 31, lines 12-33, he is silent as to use of touch screens. However, each of Kerns and Rubalcaba teach such interactive units employed with drug infusion, computer controlled medical care systems.

The systems of both teaching references employ a plurality of modules that may be operated selectively or simultaneously. Kerns teaches a touch screen (display 74) as part of control means to control

or set operating parameters of selected modules including pumped or delivery rates, times, volumes to be infused and system pressures (column 1, line 65-column 2, line 6; column 6, lines 30-51; column 8, lines 41-45 and 59-68 and column 11, lines 39-59). Rubalcaba teaches a touch screen as part of control means to control (i.e. adjust settings of) system operations such as pump infusion rates for selected modules (column 5, lines 21-29; column 6, lines 42-48 and column 6, lines 42-58).

At the time the present invention was made, it would have been obvious to one of ordinary skill in this art to have modified the Lichtenstein medical care system by supplementing or substituting at least one touch screen unit for or with the disclosed data entry devices and display units, as taught by Rubalcaba and/or Kerns, in order to prevent user confusion and error in entering data and to prevent such errors from occurring during crisis situations, as suggested by Rubalcaba (column 8, lines 35-45) and/or to prevent confusion in entering data when detaching and reattaching components, as suggested by Kerns (column 1, lines 41-59 together with column 5, lines 32-53 and column 6, lines 12-20).

Regarding these motivations, Lichtenstein discloses that different modules must be matched with corresponding support structure of the system in column 6, lines 20-29, and discloses concern with the complexity of programming required to enable appropriate data entry and control and required to match particular modules with particular programs in column 24, lines 30-55; column 31, lines 26-41 and column 31, lines 54-57).

Concerning claims 42,44,45,49-52 and 54, Lichtenstein discusses extracorporeal blood delivery and circulation and operation and control of a blood pump in column 12, lines 15-48.

Concerning claims 43-46, 52, 54 and 55, Lichtenstein discloses delivery and circulation of dialysate from a source and control of rates and pressures of pumping such dialysate in column 13, lines 38-59.

Concerning claim 47, Lichtenstein, Rubalcaba and Kerns all teach monitoring and control of a plurality of parameters which change with time, both predictably and randomly.

Concerning claim 48, see teachings of numerical keypads forming part of the touch screen in Kerns at column 5, lines 56-59 and column 8, lines 41-45 with figures 7 and 8; and see Rubalcaba at column 5, lines 24-27 with figures 5-7.

Concerning claims 53 and 55, Lichtenstein discloses control of dialysate concentration in column 14, lines 42-44.

Concerning claim 54, Lichtenstein discloses the dialysate delivery and blood delivery systems being operably coupled together through a master controller (MC) starting at column 9, lines 23-46.

Concerning claim 55, Lichtenstein discloses various memory devices and functions starting at column 8, lines 17-19 and 50-56.

Applicant's arguments filed October 27, 2003 in this application coupled with Arguments filed previously in the 09/711,240 parent application have been fully considered but they are not persuasive.

Arguments pertaining to establishing a prima facie case of obviousness under 35 U.S.C. 103 (a)

Response to Argument

It is argued that Lichtenstein does not disclose a touch screen as a user interface or suggest the need for such a touch screen. However, it is submitted that employ of complex, simultaneous medical procedures ; the need to simplify electronic and data processing components employed; and simultaneous control of multiple, interchangeable modules , all problems which would be at least partly addressed by use of a control system encompassing a controlling, interactive touch screen are addressed; see especially column 24, lines 30-55 and column 32, lines 26-62.

Response to Argument

It is argued that neither Kerns or Rubalcaba describe a hemodialysis system or any form of extracorporeal blood-treatment system or combining a touch screen with such type system. However, it is submitted that they do teach combining touch screens with medical treatment systems used in intensive care, employing multiple, interchangeable modules capable of simultaneously being operated, with such systems

including drug infusion equipment. Thus Kerns and Rubalcaba teach combining of a touch screen with medical care systems which have a plurality of features that are identical to that of Lichtenstein and which provide identical challenges.

Response to Argument

It is argued that none of the applied references provide any hint to the skilled artisan of how to develop the complex computer hardware, software, controls or displays that would be necessary to replace some or all of the conventional electromechanical controls and displays of a conventional hemodialysis system with a functioning touch screen. However, Lichtenstein explicitly discloses that development of complex hardware and software are necessary for controlling and displaying parameters for the disclosed hemodialysis extracorporeal blood treatment system in column 24, lines 30-55 and column 32, lines 26-41.

Additionally, Kerns (column 5, lines 50-55) and Rubalcaba (column 6, lines 29-32) address the need for suitable programming and sufficient memory and both throughout teach relatively complex touch screen control systems having a number of subcomponents and functions.

Response to Argument

It is argued that the expressed object in Kerns of preventing confusion of data in the switching and rearrangement of multiple modules are addressed by the teaching of making the modules identical and stackable and does not provide a suggestion for employing a touch screen. However, Kerns also teaches that the touch screen (display 74) is needed to alert the operator of mismatched modules and data and assure that modules and data are correctly matched in column 5, lines 32-59 and column 6, lines 12-20. Additionally, Lichtenstein disclose the problem of correctly arranging multiple modules with matching support structures and sensors (column 6, lines 20-29).

Response to Argument

It is argued that the motivation present in Rubalcaba to prevent user confusion and data entry is highly machine-specific, and that what causes confusion and error with a stack of infusion pump modules are not the same factors as what would cause confusion and error with modules of a medical care system employing a hemodialysis machine such as that of Lichenstein. However, it is submitted that both Lichtenstein (column 6, lines 20-29) and Rubalcaba (column 1, lines 12-19) employ multiple modules, including infusion modules, that may be employed simultaneously and thus have similar, analogous problems with managing the entry and handling of large varying quantities of data used when simultaneous medical procedures are employed.

Response to Argument

The general argument is presented stating in effect that if it were obvious to employ touch screen control systems in combination with extracorporeal blood treatment systems including hemodialysis, such touch screens would have been utilized much earlier than was actually the case. In reply, the examiner asserts that touch screens were one facet of rapidly emerging computer and data processing technology in the late 1980s and early 1990s (the time period of prosecution of the instant application). Initial adaptation of touch screens firstly to relatively simple medical equipment and then to more complex medical equipment, such as extracorporeal blood treatment systems constitutes a natural, obvious progression in the application of relatively new data processing and computer technology. *See In re Fielder and Underwood 471 f 2d. 640 176 USPQ 300 at page 305 concerning a general contemporary drive toward increasing use of automated data processing techniques being a determining factor in a question of obviousness and*

application of 35 U.S.C. @ 103. Also, Lichtenstein is concerned with use of emerging computer components, generally in column 8, lines 1-16 and column 32, lines 26-41. As acknowledged by all three of the applied references, data processing and computer control facets of medical treatment are quite complex and inherently would be ordinarily expected to require substantial periods of time to be developed within complete medical systems.

Arguments pertaining to objective evidence of secondary considerations of nonobviousness

Response to Argument

It is argued various secondary considerations of non-obviousness including commercial success, industry recognition as attested to by winning of international design awards and copying by competitors of the medical system design embodying the claimed invention (System 1000) is principally due to the development of the touch screen control system. The touch screen control system is stated to be the key feature of the System 1000 and eliminates the very large number of complicated details, and a very large number of conventional discrete controls, knobs and displays that would otherwise be necessary; and by making operation of the entire hemodialysis medical system governed by the touch screen control.

It is submitted, however, that such a touch screen control as present in System 1000 goes far beyond what is actually recited in the instant claims, which only require, at a minimum, the touch screen being operable for changing the setting of a single parameter, out of numerous possible parameters for the many components of the medical system. Nowhere, in the claims is it stated that the touch screen controls the entire operation of the medical system. Importantly, the instant claims do not preclude touch screens employing a combination of touch screen(s) and other data entry and interactive control devices, for instance, physically separate keyboards, as actually taught in Kerns et al at column 5, lines 56-59. As stated in MPEP 716.03, the commercial success must be due to claimed features, and not to unclaimed features (See *Joy Technologies Inc. V. Manbeck*, 751 F. Supp. 225, 229, 17 USPQ2D 1257, 1260 (D.D.C. 1990)).

A review of the Declaration and related documents in the file history of the parent 09/711,240 application and the grand-parent application (09/067,922) indicates that the design to which commercial success and industry recognition and awards are attributed, emphasizes several features apart from the use of a touch screen. These features included the following:

- 1) Development of a compact, integral, protective housing for the entire dialysis treatment system including hemodialysis filter, dialysate and extracorporeal blood circulation systems as well as all of the controls;
- 2) Rounded, smooth, housing surfaces allowing easy cleaning, maintenance and portability;
- 3) Easy access from the rear of the housing to service parts and components; and
- 4) Increased safety and reliability embodied in redundant sensors and software features.

The instant claims are completely silent as to claim language concerning housing features or components being integral, particular design or shape of housing or components; serving or cleaning of components or safety and reliability features. In fact, both teaching references Kerns and Rubalcaba, while employing touch screens, still present relatively complex arrangement of exposed components including cables, tubing, module support and stacking features and other stands and supports for holding fluid supplies and other components. There is no language in the claims specifying the arrangement of components, presence of a housing or any features related to safety, reliability or cleaning features.

Relatedly, it is argued that incorporation of a touch screen reduced operator training time since it could readily incorporate operator prompts and other menu driven indicia for ease of operation and minimal error. However, it is submitted that the instant claims are also silent as to incorporation of operator prompts or menu driven indicia. Further, it is readily appreciated by the ordinarily skilled artisan that such prompts and menu driven indicia are adaptable to any form of computer display or monitor module used with conventional keyboards and do not require use of a touch screen.

Response to Argument